

Appl. No. : 09/786,043
Filed : August 13, 2001

REMARKS

Applicants have amended Claims 110-112 and have added Claims 159-167. No claim is canceled. Accordingly, Claims 110-113 and 159-167 are pending. Support for Claims 160-163 is found throughout the specification in general, and particularly in Figure 2a, setting forth the boundaries of the ETS domain for SEQ ID NO:2 (hELF5), and in Figure 2b, showing mELF5 is 98% similar to hELF5. Support for Claims 159 and 164-167 is discussed in detail below.

Applicants respond below to all the objections and rejections raised by the Examiner in the Office Action of May 5, 2004.

Objections to Claim 110

Claim 110 stands objected to for allegedly not being as clear as possible. The Examiner suggests amending Claim 110 into two different claims, one being drawn to the nucleotide sequence encoding SEQ ID NO:2 and another claim drawn to a nucleotide sequence complimentary to the nucleotide sequence encoding SEQ ID NO:2. While Applicants do not agree that the claim is unclear, Applicants nevertheless have endeavored to comply with the Examiner's suggestion. Claim 110 is now directed to the nucleotide sequence encoding SEQ ID NO:2. New Claim 159 is directed to a nucleotide sequence complimentary to the nucleotide sequence encoding SEQ ID NO:2.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 110-112 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement.

The Examiner alleges that the recitation of "45% similar to SEQ ID NO:2" creates a very large genus which encompasses molecules which do not have the same function as the amino acid sequence set forth in SEQ ID NO:2. The Examiner further alleges that even though those of ordinary skill in the art would readily recognize a polypeptide having an ETS domain, they would not be able to recognize which of the polypeptides having an ETS domain would have transcriptional activity without performing further experimentation. See Office Action, page 5.

Applicants respectfully traverse. The present specification discloses actual reduction to practice of at least three species of the nucleotide sequences that fall within the scope of the claims. See, for example, table on page 49. These species are representatives of the claimed

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genus because they all have at least 45% structural identity with the reference compound, i.e., SEQ ID NO:2. All of these species also share greater than 98% identity across the ETS domain. As is explained throughout the specification, the ETS domains are extremely distinctive between the different families of molecules which are characterized by an ETS domain. In fact, the most significant similarity between members of such a family occurs in the ETS domain, such that if any significant differences exist between the ETS domains of two molecules, these molecules are sufficiently structurally and functionally different such that they are not deemed to belong to the same family. Consequently, mere identification of the ETS domain of individual polypeptide molecules, a feat that the Examiner concedes to be within the skill of the ordinary artisan, allows those of skill in the art to identify the function of the polypeptide molecule as well and determine whether the various polypeptide molecules share the same functional characteristics. Additionally, the present specification provides an assay in Example 17 on page 61 for identifying all of the variants of SEQ ID NO:2 that have an ETS domain and are capable of performing the cellular function set forth in the specification. Therefore, Applicants respectfully submit that the claims having the “45% similarity” limitation are fully compliant with the written description requirements.

However, in order to expedite prosecution and advance the case towards allowance, Applicants have amended Claims 110 and 112 to be limited to the full-length sequence of SEQ ID NO:2, and have added Claims 164-167 directed to variants having 95% similarity to SEQ ID NO:2. Support for this limitation is found in the specification, *inter alia*, at page 51, lines 1-2. Applicants respectfully submit that the facts set forth above along with the “95% similarity” limitation put these claims squarely within what is considered sufficient written description, as set forth in Example 14 of the Written Description Guidelines, which indicates that disclosure of a single species (Applicants disclose at least three species) with variants having 95% similarity, and disclosure of a function along with an assay that helps the skilled artisan to identify the function (such as that provided in Example 17 of the present specification) is considered sufficient written description under 35 U.S.C. § 112, first paragraph.

The Examiner also alleges that the specification has not disclosed any critical elements of SEQ ID NO:1 which confer the desired function to the sequence. Applicants respectfully traverse this point as well. The specification discloses molecules exhibiting SEQ ID NO:1 sequence and those hybridizing under medium stringency conditions to SEQ ID NO:1. Any

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molecule which hybridizes to SEQ ID NO:1 under medium stringency conditions will exhibit the same functional activity as ELF5. Only nucleic acid molecules closely complementary to SEQ ID NO:1 will bind under these conditions. Accordingly, it would not be necessary to perform any additional experimentation in order to identify the structural elements which are critical to the function of SEQ ID NO:1 related molecules.

The Examiner further alleges that Claims 110-112 fail to comply with the enablement requirements of 35 U.S.C. § 112, first paragraph. The Examiner alleges that one of skill in the art must perform undue experimentation to identify the minimal critical elements common to all members of the genus.

Applicants respectfully traverse. As for the claims that are now directed to the full-length sequence of SEQ ID NO:2, Applicants respectfully submit that the rejection is now moot, as the Examiner himself has suggested that limiting the claims to full-length sequence would obviate the rejection. See, page 7 of the Office Action..

As for the claims directed to the 95% variant of SEQ ID NO:2, Applicants respectfully submit that it is well within the skill of those of ordinary skill in the art to identify polypeptide molecules having a sequence 95% similar to that of SEQ ID NO:2, identify its ETS domain (as the Examiner himself acknowledges on page 5 of the Office Action), and determine its function using the directions set forth in the specification in general and specifically in Example 17.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw all of the rejections under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 102(b)

Claims 110-112 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Buchert (BBRC, 1998, Vol. 246, pp. 176-181).

Applicants respectfully traverse. Applicants have amended the claims to recite “*the* amino acid sequence as set forth in SEQ ID NO:2” as opposed to “*an* amino acid sequence as set forth in SEQ ID NO:2.” Applicants respectfully submit that with this change the present claims do not read on the very short amino acid sequences that the Examiner cited in the Office Action.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw all of the rejections under 35 U.S.C. § 102(b).

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CONCLUSION

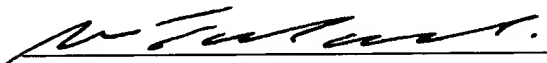
Applicants have endeavored to respond to all of the Examiners comments and rejections. Applicants respectfully submit that the claims, as amended herewith, are patentable and should be passed to issue. A notice to that effect is respectfully requested.

Applicants have submitted a check in the amount of \$490 for a three month extension of time. If the fee is incorrect, please charge any additional fees or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Nov. 4, 2004

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